K120196

APR 19 2012

510(k) Summary
(in accordance with 21 CFR 807.92)

510(k) Number K_____

I. Applicant Information

Applicant:

OLEA MEDICAL
93 avenue des Sorbiers, Zone Athelia IV
La Ciotat 13600
France

Contact Person: Caroline Lene
Quality Manager
Tel: (011) 33 4 42 71 24 20
Fax: (011) 33 4 42 71 24 27
e-mail: caroline.lene@olea-medical.com

Application Correspondent:

EMERGO GROUP INC.
611 West 5th Street, Third Floor
Austin, TX 78701
U.S.A.

Contact Person: Kristi Gusman
Project Manager
Tel: (512) 327-9997
Fax: (512) 327-9998
e-mail: kristi@emergogroup.com

Date Prepared: November 30, 2011

II. Device Name and Classification

Proprietary Name:	Olea Sphere
Common/Usual Name:	PACS
Classification Name:	Picture Archiving Communications System
Regulation Number:	21 CFR 892.2050
Product Codes:	LLZ
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Devices

The Olea Sphere device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K090546
Trade Name:	**Nordic Image Control and Evaluation (nordicICE) Software**
Manufacturer:	NordicImagingLab AS
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	21 CFR 892.2050
Product Codes:	LLZ
Classification:	Class II

The software architecture of many of the features of the Olea Sphere is essentially identical to that used by the following FDA cleared predicate device:

510(k) Number:	K111161
Trade Name:	**Perfscape V2.0**
Manufacturer:	Olea Medical
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	21 CFR 892.2050
Product Codes:	LLZ
Classification:	Class II

For completeness, both predicate devices have been included for comparison purposes.

IV. Device Description

Olea Sphere is a medical viewing, analysis and processing software package (PACS) compliant with the DICOM standard and running on Windows, Macintosh or Linux operating systems.

Olea Sphere allows the display, analysis and post-processing of medical images.

These images, when interpreted by a trained physician, may yield clinically useful information.

The software provides a wide range of basic image processing and manipulation functions, in addition to comprehensive dynamic image processing and display.

The main features of the software are:

- Image Loading & Saving
- Image Viewing
- Image Manipulation
- Image Analysis
- Imaging Processing
- Perfusion Post-processing
- Permeability Post-processing
- Diffusion Weighted Image / Tensor Image Post-processing
- Fiber Tracking Post-processing

The main users of the program are medical imaging professionals who need to visualize and analyze images acquired primarily with MRI or CT systems. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

V. Intended Use

Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes

the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

VI. Summary of the Technical Characteristics

Olea Sphere is a PACS software designed to access series of MRI and CT perfusion and diffusion images in DICOM format. The system utilizes the information contained in each image meta-data to compare images and to perform zoom, pan and crop functions.

Olea Sphere offers a viewing and analysis module that allows to display simultaneously available DICOM image datasets and to save the results into the DICOM database.

Olea Sphere offers four types of display for a particular data set:

1. The multi-slice view displays simultaneously all the images of selected series in tabular format where rows represent image series and columns represent cross-sectional levels;

2. The mono-slice view displays simultaneously one image of selected series at a given slice location;

3. The MPR/3D view displays selected series in a three dimensional projections;

4. The follow-up view displays images of series acquired over time.

The system allows the calculation of surfaces and volumes over a set of unfiltered images by using "segmentation masks". This also allows the user to optimize selected images by customizing the segmentation masks based on

user defined areas and to save the results of this image optimization into PDF format files.

The following **Predicate Device Comparison Table** provides a summary of the comparison between the Olea Sphere and the predicate devices listed in Section III, with respect to intended use, environment of use, limitations of use, principles of operation and performance characteristics. More detailed information regarding the basis for the determination of substantial equivalence can be found at Section 12 of this 510(k) submission.

Predicate Device Comparison Table

Product Code	LLZ	LLZ	LLZ	None.
Regulation #	892.2050	892.2050	892.2050	None.
Class	II	II	II	None.
Intended Use	Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets	Nordic Image Control and Evaluation (nordicICE) Software is an image processing software package to be used by trained professionals including but not limited to physician and medical technicians. The software runs on a standard "off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data are images acquired through DICOM compliant imaging devices and modalities. nordicICE provides both viewing and analysis capabilities of functional and dynamic imaging datasets	PerfScape V2.0 is a PACS system that allows the display, analysis and post-processing of dynamically acquired Magnetic Resonance (MRI) and Computed Tomography (CT) datasets to evaluate image intensity variations over time. PerfScape V2.0 retrieves and accepts data from existing MRI and CT systems. Based on these data, PerfScape V2.0 performs quality control checks, displays Diffusion Weighted Images (MRI only) and generates parametric maps such as Relative Blood Volume, Relative Blood Flow, Relative Mean Transit Time, Time to Peak, Impulse	Olea Sphere and nordicICE have essentially an identical Intended Use, with the exception that Olea Sphere does not include the BOLD fMRI analysis feature (see part in yellow). Olea Sphere and PerfScape V2.0 have substantially equivalent Intended Use, with the exception that PerfScape V2.0 is only limited to the post processing of perfusion datasets (CT or MRI), diffusion datasets and diffusion tensor imaging.

[redacted]

	acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.	acquired with MRI or other relevant modalities, including blood oxygen level dependent (BOLD) fMRI, diffusion weighted MRI (DWI) / fiber tracking and dynamic analysis. [redacted] DWI/Fiber Tracking: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilize the directional dependency of the diffusion to display the white matter structure in the brain.	Response Time to Peak, permeability and leakage between intravascular and extracellular space (MRI only), and temporal Maximum Intensity Projection (CT only). PerfScape V2.0 also generates Diffusion Weighted Images and/or Diffusion Tensor Images (MRI only). These images, when interpreted by a trained physician, may yield clinically useful information. PerfScape V2.0 is compliant with the DICOM standard allowing the system to visualize medical images. The system is a multiplatform software running on Windows, Mac and Linux operating systems.	

	The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as: Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.	Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as: nordicICE Perfusion Module - Calculation of parameters related to tissue flow (perfusion) and tissue blood volume. nordicICE DCE Module - Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.		
Environment of Use	Olea Sphere is for use in hospitals, imaging centers, radiologist reading practices	Nordic Image Control and Evaluation (nordicICE) Software is for use in	PerfScape V2.0 is for use in hospitals, imaging centers, radiologist reading practices	None.

	by professional who requires and is granted access to patient image, demographic and report information.	hospitals, imaging centers, nursing homes and radiologist reading practices by any user who requires and is granted access to patient image, demographic, and report information.	by professional who requires and is granted access to patient image, demographic and report information.	
Limitations of Use	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.	None.
Principles of Operation	The Olea Sphere software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. Olea Sphere provides both viewing and analysis	The nordicICE software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. nordicICE provides both viewing and analysis	The PerfScape V2.0 software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. PerfScape V2.0 provides both viewing and analysis	Olea Sphere and nordicICE have essentially identical Principles of Operation, with the exception that Olea Sphere does not include the BOLD fMRI analysis feature (see part in yellow). Olea Sphere and PerfScape V2.0 have

	capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis (dynamic contrast enhanced imaging data for MRI and CT).	capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including [redacted], diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis.	capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI), and dynamic analysis (contrast enhanced imaging data for MRI and CT).	essentially identical Principles of Operation, with the exception that PerfScape V2.0 does not include the Fiber Tracking and the DCE/Permeability processing and analysis tools.
	DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white	DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white	DWI / DTI Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.	

	matter structure in the brain or more generally the central nervous system. Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary	matter structure in the brain. Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary	Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary	

	permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as: Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.	permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as: Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space	permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as: Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume.	
Performance Characteristics	Main software features: • Image Loading & Saving; • Image Viewing; • Image Manipulation; [redacted] • Image Processing; • Perfusion Maps;	Main software features: • Image Loading & Saving; • Image Viewing; • Image Manipulation; [redacted] • Image Processing; • Perfusion Maps;	Main software features: • Image Loading & Saving; • Image Viewing; • Image Manipulation; • Image Processing; • Perfusion Maps;	All three devices perform in a substantially equivalent manner, with the exception that in Perfscape V2.0 no Image Analysis, Fiber Tracking and

	• Diffusion Weighted Imaging/Tensor Imaging Maps;	• Diffusion Weighted Imaging/Tensor Imaging Maps;	• Diffusion Weighted Imaging/Tensor Imaging Maps.	Permeability Maps features are available (see part in yellow).

VII. Summary of Testing

OLEA Medical has conducted extensive validation testing of the Olea Sphere system, as a PACS that is capable of providing reliable post-processing and display of images for instantaneous multi-parametric analysis. All of the different components of the Olea Sphere software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use.

The tests performed included:

- Product Risk Assessment
- Software modules verification tests
- Software validation test

VIII. Conclusions

Based on the comparison of intended use and technological characteristics, the Olea Sphere system is substantially equivalent to the Nordic Image Control and Evaluation (nordicICE) Software manufactured by NordicImagingLab AS (K090546).

Additionally the software architecture of many of the features of the Olea Sphere is essentially identical to that one of the Perfscape V2.0 software manufactured by Olea Medical (K111161).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OLEA Medical
% Ms. Kristi Gusman
Project Manager
Emergo Group Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

APR 19 2012

Re: K120196
Trade/Device Name: Olea Sphere
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 30, 2011
Received: January 23, 2012

Dear Ms. Gusman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indication for Use Statement

510(k) Number (if known): _____

Device Name: **Olea Sphere**

Indications for Use:

Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120196